

REMARKS

Claims 34-37, 39, 41, 43, 44 and 71, as amended, remain herein.

Claims 34-36, 41 and 43 have been amended. Those amendments are supported by applicant's specification at, for example, page 4, line 13 and page 5, line 5, through page 9, line 16. Those claims have been amended to clarify that the claimed drug delivery device consists of a substantially hollow seed for implantation, and has an opening in each end thereof to provide controlled diffusion of a therapeutic agent from the hollow seed. New claim 71 is supported by applicant's specification page 15, lines 12-13.

1. Claims 34-36, 39, 41, 43 and 44 were rejected under § 103(a) over Lyle '713 in view of Crocker '742.

Lyle '713 discloses a composition and method of therapeutic treatment for inhibiting vascular restenosis. Lyle, col. 4, lines 35-40 disclose administering in vivo an antisense polypeptide or oligonucleotide or molecule having similar specificity by using a balloon infusion catheter with holes in it for delivery to the particular target site to prevent life-threatening restenosis. However, this is the only description of a "balloon infusion catheter with holes in it" in Lyle '713. Lyle '713 does not disclose a substantially hollow seed for implantation into a tissue or organ, which seed has an opening at each end thereof for providing controlled diffusion of a therapeutic agent from such hollow seed.

Thus there is no disclosure or teaching in Lyle '713 of all elements of applicant's claimed invention, and there is no disclosure or teaching in Lyle '713 which would have suggested applicant's claimed invention to one of ordinary skill in the art.

Crocker '742 discloses a radiation delivery balloon for a balloon catheter that includes a central zone 32 and proximal zone 28. At an inflation pressure of about 8 atm., the proximal zone 28 has an outside diameter of about 3 mm and the central zone 32 has an outside diameter of about 3.4 mm. As shown in Figs. 3 and 4, a large zone 32 is provided with a radiation source 34 surrounded by outer sleeve 38. Alternatively, the outer sleeve 38 can be omitted, and radiation source 34 adequately secured to the exterior of the balloon.

However Crocker, like Lyle, does not disclose hollow seeds for implantation into a tissue or organ, which seeds have an opening at each end thereof. Indeed, the balloon catheters mentioned in both Lyle and Crocker are not seeds for implantation, and cannot be used for same because it is necessary to have central guide wire running through both ends of such balloons and securing them to the catheter.

Thus, there is nothing in either Lyle or Crocker which in any way suggests a hollow seed for implantation, let alone such a seed for implantation having an opening at each end thereof, to provide controlled diffusion of a therapeutic agent out of the hollow seed. Nor is there any disclosure or teaching in either Lyle or Crocker which would have suggested the desirability of combining any portions thereof effectively to anticipate or suggest applicant's presently-claimed invention. Accordingly, reconsideration and withdrawal of these grounds of rejection are respectfully requested.

2. Claims 34-47, 39, 41, 43 and 44 were rejected under § 112, second paragraph, the Office Action alleging that the recitation of "a nucleic acid sequence" in independent claim 34 is indefinite.

Applicant's specification, page 15, line 7-16, explains this limitation in applicant's claimed invention, saying that the claimed seed will comprise "a therapeutic nucleic acid sequence, e.g., a radiation-sensitizing gene, antisense DNA, ribozyme, virus, plasmid, et seq." The term "nucleic acid sequence" is well-known in the genetic engineering art. Even the Lyle '713 reference cited in the Office Action makes it clear that "it is not necessary that the entire oligonucleotide sequence be present." Lyle '713, col. 4, lines 31-32. The Office Action seems to imply that it would be necessary to recite a whole molecule for such a term to satisfy § 112, second paragraph. Lyle '713, as well as applicant's specification, demonstrate that this premise is in error. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

For all the foregoing reasons, all claims 34-37, 39, 41, 43, 44 and 71 are now patentably distinguished over all grounds of rejection cited in the Office Action. Accordingly, allowance of all claims is respectfully requested.

The PTO is hereby authorized to charge/credit any deficiency/overpayment to Deposit Account No. 19-4293 (Order No. 28964.0054). Should the Examiner believe that further changes would place this application in even better condition for issue, the Examiner is invited to telephone applicant's undersigned attorney.

Respectfully submitted,

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April 24, 2006

RWP/tlpdg
Atty Dkt: 28964.0054

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